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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,600	05/23/2001	Virginia Smith-Swintosky	PRI-0014 (ORT-1436)	9298

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EXAMINER	
MOHAMED, ABDEL A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/863,600	SMITH-SWINTOSKY ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *55-58* is/are allowed.

6)☒ Claim(s) *38-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/6/05, 6/3/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/24/05 has been entered.

ACKNOWLEDGMENT OF AMENDMENT, REMARKS, IDS AND STATUS OF THE CLAIMS

2. The amendment, remarks filed 05/24/05 and information disclosure statement (IDS) and Form PTO-1449 filed 01/06/05 and 06/03/05 are acknowledged, entered and considered. In view of Applicant's request claims 53-58 have been added. Claims 38-58 are now pending in the application. The rejection under 35 U.S.C. 112, first paragraph is maintained for the reasons of record.

ARGUMENTS ARE NOT PERSUASIVE

CLAIMS REJECTION-35 U.S.C. 112 1st PARAGRAPH.

3. Claims 38-52 and newly submitted claims 53 and 54 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for employing peptides comprising one or more monomeric peptides that bind to erythropoietin (EPO) receptor and use of said peptides in designing, synthesizing and testing of biological activity toward the EPO receptor *in vitro*, does not reasonably

provide a method for treating a patient having a condition mediated by neurotoxicity, neurodegeneration or neurological damage by administering to said patient (which include humans) therapeutically effective amount of the specific compounds in the manner claimed in claims 38-51, to a method of promoting neurite outgrowth in a patient having a condition mediated by neurotoxicity, neurodegeneration or neurological damage by administering to said patient effective amount of the specific compounds as claimed in claim 52, and to a method for promoting neurite outgrowth in a patient by administering to said patient an effective amount of the specific compounds as claimed in claim 53 and 54. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's arguments filed 05/24/05 have been fully considered but they are not persuasive. Applicant has argued that 1) the Examiner has not provided a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure; 2) that the legal standard imposed by 35 U.S.C. 112, first paragraph has been met because Applicant describes the compounds and methods of making and using them in sufficient detail to allow one of ordinary skill in the art to make and use the compounds for the claimed methods. Thus, Applicant through sufficient information, detailed objective guidance and examples teaches the manner and process of making and using the invention in terms commensurate in scope with the claims; 3) the claims in questions (i.e., claims 38-54) are enabled; 4) Applicant further states that the Office action provides no reason to believe that the skilled practitioner, after reading

the present application, and in particular, the data demonstrating that the disclosed EPO mimetics stimulate neurite outgrowth, would have any trouble (1) believing that the EPO mimetics, like EPO, possess neuroprotective activity and (2) adapting protocols used for treatment with EPO for use with the EPO mimetics. As provided on page 23 of the Genc reference (Genc et al Brain Research, 2000 19-31), multiple models of nervous system injury in animals have been used in combination with EPO. These models easily and routinely be adapted for use with the disclosed EPO mimetics, and cites *In re Brana*, 51 F.3d 1560, 1567-68 *Fed. Cir. 1995); *In re Fouche*, 169 USPQ 429, 434 (CCPA 1971); 5) Applicant acknowledges that the references filed 08/11/04 as Exhibits A and B were provided to demonstrate the nexus between EPO and the treatment of conditions mediated by neurotoxicity, neurodegeneration, or neurological damage; and 6) Applicant concludes by stating that taken as a whole, it is seen that the supporting disclosure is commensurate in scope with the methods as claimed, and as such, there is insufficient evidence to support the rejection as set forth in the Official Action, that one having ordinary skill in the art could practice the claimed invention without undue experimentation, and that the requirements of the first paragraph of 35 U.S.C. 112 have been met is unpersuasive.

Contrary to Applicant's arguments as discussed in the previous Office action of 04/29/04, the Examiner has shown that the specification provides evidence that the recited EPO mimetic peptides stimulate neurite outgrowth in cell culture and that EPO has neuroprotective activity; however, for the reasons discussed previously, the peptides cannot be expected to be useful at promoting neurite outgrowth in a patient or

treating a patient having a condition that can benefit from neurite outgrowth such as conditions mediated by neurotoxicity, neurodegeneration, or neurological damage in the manner claimed in the instant invnetion.

In regard to Applicant's assertion that Applicant has provided data in the specification demonstrating the nexus between EPO and/or EPO mimetics and treatment of the recited conditions and cited for example, Cerami et al. Nephrol Dial Transplant 2002; 17 Suppl 1: 8-12 (enclosed as Exhibit A) and Genc et al., Brain Research, 2000 19-31 (enclosed as Exhibit B) to support the nexus between EPO and the treatment condition claimed is unpersuasive. Contrary to Applicant's assertion, the cited references by Applicant (i.e., Exhibits A and B) do not teach or disclose the claimed method of treating a patient having a condition mediated by neurotoxicity, neurodegeneration or neurological damage by administering to said patient (particularly human) a therapeutically effective amount of a peptide comprising one or more monomeric peptides claimed. Further, as discussed in the previous Office action, the prior art clearly show the unpredictable nature and the complexity of the art in regard to treatment and/or promotion of neurite outgrowth of CNS disorders which include Alzheimer's disease, Parkinson's disease, Down's syndrome, Huntington's disease, etc. Therefore, considering the nature of the treatment and/or promotion of neurite outgrowth of CNS disorders and/or diseases by administering a therapeutically effective amount of the peptide claimed and the limited success achieved; one skilled in the art would not accept the instantly claimed invention as obviously valid and correct without demonstration of working example(s) or evidence or data for the following reasons:

In view of the fact that animals and humans are out bred, in view of the lack of disclosure of suitable animal models for a method of treating and promoting neurite outgrowth of CNS disorders or conditions or diseases, in view of the recognized problems in the art regarding effective treatment of diseases affecting the nervous systems (neuropathologies) and in view of the fact that it is difficult to regenerate the neurons in the living body; a reasonable doubt exists as to the enablement of the claimed method of treating a patient having a condition mediated by neurotoxicity, neurodegeneration or neurological damage by administering to said patient (particularly human) a therapeutically effective amount of a peptide comprising one or more monomeric peptides claimed. Thus, the claims are based on pure speculation that the method would be effective since Applicant has not established any nexus between an effective amount of the claimed peptides and its use in the manner claimed.

Therefore, in view of the above, and in view of the fact that there is no enablement in the instant specification for methods of treating and promoting neurite outgrowth diseases of the nervous system by administration of composition having the neurological therapeutic activity of EPO; Applicant should present some data or evidence to establish the successful use of a method for treating and promoting neurite outgrowth in a patient having a condition mediated by neurotoxicity, neurodegeneration or neurological damage by administering the claimed peptide to a patient in order to fulfill 35 U.S.C. 112, first paragraph requirement. Secondly, the Examiner has clearly shown in the previous Office Action of Paper No. 23 (mailed 11/20/03) and Final Office action mailed 4/29/04 that without guidance through working example(s), one of

ordinary skill in the art would not predict from background discussion and/or information and protocols to employ or administer the pharmaceutical formulation in therapeutically effective composition in the manner claimed. Thus, the specification does not enable any person skilled in the art to which it pertains, or which it is most nearly connected, to use the invention commensurate in scope with the claims. In the express absence of one or more examples, evidence and sufficient guidance, the skilled artisan would be faced with undue experimentation for practicing the invention. Thirdly, it is not understood from Applicant's response how the instant invention, which Applicant considers as novel and inventive, be exemplified without working example(s) or data or evidence. The law requires that a disclosure in an application shall inform those skilled in the art how to use Applicant's alleged discovery, not how to find out how to use it for themselves. See In re Gardner et al, 166 USPQ 138 (CCPA 1970). Therefore, undue experimentation is necessary to determine if and under what conditions, the claimed invention as broadly claimed is enabled. Hence, it is viewed that the specification does not enable the invention as claimed in claims 38-54, as it does not teach how to use the invention to achieve the function of the claims for the reasons discussed above. Thus, applying the Wands factors to the facts of this case, one of skill in the art would find that undue amount of experimentation would be required to practice the full scope of the extremely broad claims for the reasons given above. Hence, in view of the quantity of experimentation necessary, the lack of adequate guidance or working examples or data, and the breadth of the claims, the claims are not commensurate in scope with the enabling disclosure. Accordingly, filing of evidence commensurate with the scope of the

claims or amendment of the claims to what is supported by the enabling disclosure is again suggested.

ACTION IS FINAL, FIRST ACTION FOLLOWING REQUEST FOR CONTINUED EXAMINATION UNDER 37 CFR 1.114

4. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, THIS ACTION IS MADE FINAL even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

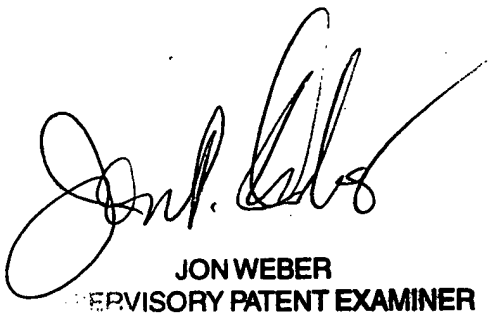
CONCLUSION AND FUTURE CORRESPONDENCE

5. Claims 38-54 are rejected and claims 55-58 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CAMPELL BRUCE can be reached on (571) 272 0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JON WEBER
ERVISORY PATENT EXAMINER

Mohamed/AAM
July 20, 2005